Stockholm University

20 February, 2018

Transparency register: 514687319814-91

Baltic Sea Centre's reply to DG ENV's consultation on the pharmaceuticals in the environment

General comments

We welcome the effort to limit emissions of pharmaceuticals to the environment and that the policy options proposed address all stages of the pharmaceutical substances' lifecycle.

- Many options are of the type "encourage" an action, "strengthen" resources or "establish a dialogue" or guidelines, which makes it difficult to evaluate the anticipated outcome in terms of reduced emissions of pharmaceuticals. When comparing the different policy options, initial cost-efficiency calculations at EU or at least national level would have been helpful to be able to compare the potential for each measure.

  For example, having estimations for the possible reduction of pharmaceutical use due to imposed prescription requirements for current over the counter pharmaceuticals (e.g. diclofenac), as well as estimations for the magnitude of general over-prescription. Or how the amount of pharmaceuticals incorrectly disposed of down the drain compares to the amount excreted after human use.

  It would further have been useful with a specification of the end effect for active pharmaceutical ingredients (APIs) disposed of in household garbage. Such as the fraction that ends up in landfills, and if APIs are degraded at temperatures prevailing during normal waste combustion.

  Is there an estimation of the amount of pharmaceuticals in the environment originating from incorrect disposal?

- We encourage the Commission to suggest more stringent legal requirements to combat overuse of antibiotics and emissions of these substances from manufacturing, also outside the EU. This category of APIs should be considered separately from pharmaceuticals in general as the functioning of these substances is threatened by over- and incorrect use with the emissions to the environment having consequences for humanity.

- Pharmaceuticals in the environment should not be treated in isolation from other chemical contamination. This needs to be taken into consideration in the cost-benefit analysis of policy options that offer the possibility to remove a wide range of chemical

Stockholm University Baltic Sea Centre

Stockholm University
Baltic Sea Centre
106 91 Stockholm
SWEDEN

Visiting address:
Svante Arrhenius väg 20 F
www.balticeye.org

Phone: +46 8 16 37 18
Telefax:
E-mail: balticeye@su.se

Stockholm University

pollutants and reduce environmental effects, such as downstream measures like advanced wastewater and sludge treatment.

Specific comments

Option 9

As it is known which substances that are produced at different production sites, it is clear which substances that should be monitored in production effluents and further downstream. Hence, stricter requirements on the quality of wastewater from production sites should technically not be difficult to implement.

As regards the definition of standards for emissions, it needs to be ensured that allowed concentrations of antibiotics in industrial wastewater are well below concentrations that exert a selection pressure on bacteria.

In a future revision of the Industrial Emission Directive (IED), we would like to see an inclusion of antibiotics as priority pollutants.

Option 18

A fundamental difficulty is which pharmaceutical substances to prioritise, something that is also identified here under Threats: which substances that should be put on the watch list and which API that should be included in the IED. The strategy should include actions that enable better prioritisation of APIs based on environmental risk such as targeted research in the fields of early warning, screening and prioritisation.

Option 19 and 20

Measures aiming to reduce consumption of pharmaceuticals with known risks to the environment by raising the awareness of the general public and educating professionals to prescribe better alternatives requires that a) we know which pharmaceuticals that have unacceptable environmental impacts and that b) the substitute API has a similar health benefit. This as weighting human health needs against environmental issues can be difficult or unethical. This would require that comparable environmental risk assessments are performed for all APIs, also those put on the market before 2005-2006, and that results are shared among Member States and preferably made publically available. Hence, several proposed policy options need to be implemented to enable adequate information campaigns.

Stockholm University

Option 22

Collection systems for unused pharmaceuticals can constitute an efficient way to prevent pharmaceuticals from e.g. being flushed down the drain. But to evaluate the environmental impact of waste collection schemes it would be interesting to see data on how large a fraction of pharmaceuticals that is disposed of in toilets versus thrown in household trash. And if the latter, to what extent pharmaceuticals survive incineration.

Advanced wastewater treatment

Even though EU and national level funding schemes are positive, what is truly needed to ensure better treatment of wastewater is to incentivise it through legislation, something that is briefly mentioned under some of the options. As is the case for nutrients and organic matter today, treatment efficiency requirements or threshold levels of concentration of chemicals could be included in new legislation related to wastewater such as the revision of the Urban Waste Water Directive or in legislation for water reuse. Increased demands can be put on large facilities where absolute emissions are high and costs per treated volume of water are lower due to upscaling effects.

As touched upon above, the consultation is focused on pharmaceuticals specifically and not on chemical substances present in wastewater in general. However we argue that this type of end of pipe solution should take all micropollutants into consideration and be viewed in a broader cost-efficiency perspective in line with the precautionary principle. This as it also relates to other societal services such as protecting drinking water and protecting agricultural land when reusing wastewater for irrigation.

It should be stressed that a large fraction of emitted mass of APIs comes from human use followed by excretion, and that these emissions to some extent are inevitable. In densely populated areas, end of pipe measures will likely be necessary to reduce environmental concentrations. This should be acknowledged in the analysis.

Option 24

Under *Context* is reads that hospitals and healthcare centres generally make a very low contribution to total wastewater discharges when compared to households, but that for certain pharmaceuticals the contribution can reach a much higher share of the overall pharmaceutical environmental load.

This means that from a societal perspective an overall cost-benefit analysis is needed if having to choose between different options, such as advanced wastewater treatment for hospitals or urban advanced wastewater treatment. This to ensure that the most cost-effective way of decreasing the total environmental load is found.

When specific compounds are identified to be particularly problematic in the environment, source control is often the best option.

Stockholm University

Option 25

Data for identification of hotspots for development of antibiotic-resistant bacteria is highly needed. We would have liked to see an extended discussion and focus on the relative importance of overuse and incorrect use (e.g. over-prescriptions and interrupted treatment in humans, preventive use in animal husbandry) and emissions to sewers and the environment (water and soil) in order to determine the potential of various measures to tackle the problem of antimicrobial resistant (AMR) microorganisms.

Problems associated with emissions of many pharmaceuticals arise after emissions occur in the environment, whereas AMR mainly arise in earlier stages of the antibiotics' lifecycle, e.g. in human bodies, in animals, in sewers where concentrations are high, or downstream production facilities with insufficient treatment of wastewater. This means that tackling the problem of antibiotic resistance relies more heavily on upstream measures.

Options 26

We would like to point out that it is not entirely clear when reading the text that different or complementary technological solutions may be needed to reduce pharmaceuticals and AMR microorganisms. Advanced treatment technologies that do not disinfect the water do not efficiently reduce the presence of antimicrobial resistant microorganisms in effluents. Even though the levels of antibiotics in the outgoing water are reduced, this does not necessarily mean that antimicrobial resistance is reduced.

Under Weakness for both option 26 and 27 it says that the technology may not be effective for future compounds. We would have liked to see an explanation of what is meant by this.

Option 27

We are positive to the suggestions presented under Description. In addition to funding possibilities, we are positive to encouraging Member States to monitor Water Framework Directive (WFD) priority substances to a larger extent than today in order to complete the assessment of good environmental status. We would also like to see an extension of the risk assessment and monitoring of environmental pollutants being included in future programmes of measures for the WFD. Assisting Member States in achieving full policy coherence and implementation of the Water, Marine and Urban Wastewater Directives would help in this regard.

The costs identified by Eureau in 2014, saying that costs could increase by 18 to 70€ per person/per year contrast with the Swedish EPA's report on advanced wastewater treatment from 2017 which estimates total costs to 5 – 49€ per household/per year. The Swedish report states: An attempt to extrapolate costs to all WWTPs in Sweden (greater than 2,000 PE) means an estimated total cost of between approximately 241 million and 2.1 billion Swedish kronor per

Stockholm University

year. This corresponds to approximately 55-480 kronor per household per year. Under the assumption that there are 431 WWTPs greater than 2,000 PE in Sweden (Swedish EPA and Statistics Sweden, 2016). The dimensioning flow is also assumed to be 150 m3/(PE, year)[1].

[1] From the Swedish EPA report 6766: *Advanced wastewater treatment for separation and removal of pharmaceutical residues and other hazardous substances: Needs technologies and impacts.*